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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/894,356	08/18/1997	TOSHIHIKO ASHIKARI	001560-308	8892

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/894,356	ASHIKARI ET AL	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/05/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-12,20,22-41,46-52 and 54-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-12,20,22-41,46-52 and 54-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/05/2003 has been entered.

Claim 1 has been amended. Claims 1-3, 5-12, 20, 22-41, 46-52 and 54-66 are pending and are considered. Applicant's amendment and arguments have been fully considered, but are not deemed persuasive for the reasons set forth below. All previous rejections and objections not set forth below have been withdrawn in view of Applicant's amendment.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 5-8, 28-41, 46-52 and 54-66 are objected to because SEQ ID NOs: 1 to 6 are DNA sequences not amino acid sequences. Appropriate correction is required.

At claims 9, 25, 29, 33, 36, 55 and 62 "a polynucleotide" should be changed to --- the polynucleotide--- because it refers to a previous claim.

At claims 25 and 62, "tissues thereof" refers to the plant or the progeny.

At claim 27, "plants progeny" should be changed to --plant's progeny---

At claims 10, 30 and 56, "a vector" should be changed to ---the vector--- because it refers to a previous claim.

At claim 32, what is a plant body?

At claims 26 and 63, flower is not a tissue.

Claims 46-52 do not further limit parent claims.

At claims 56-58, "host" should be changed to ---host cell--.

Claim Rejections - 35 USC § 112

Claims 1-3, 5-12, 20, 22-41, 46-52, and 59-66 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 39-41, and 46-52 recite a polynucleotide that encodes an anthocyanin acetyltransferase; claims 5-8 recite the same polynucleotide encodes a protein that transfers an aromatic acyl group to flavonoid; claims 20 and 22-23, 33-35 recite the same polynucleotide expresses a protein that acylates the pigment in the plant; claim 28 recites the same polynucleotide encodes anthocyanin acyltransferase that transfers an aromatic acyl group to flavonoid. Appropriate correction is required to more clearly define the metes and bounds of the claims.

Claim 2 is indefinite in the recitation of "using" without positive method steps.

Claims 59-61 are indefinite because "said gene" lacks antecedent basis. Dependent claims 65-66 are included in the rejection.

Claims 62- and 64 are indefinite in the recitation of "the same property because it is unclear what property is being referred to.

At claim 63, "the plant tissue" lacks antecedent basis.

Claim Rejections - 35 USC § 112

Claims 1-3, 5-12, 20, 22-41, and 46-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polynucleotides encoding SEQ ID NO: 1-6, a vector, host cells, plants/plant cells comprising said polynucleotides, and a method of transforming plants with said vector does not reasonably provide enablement for an isolated polynucleotide encoding any anthocyanin acyltransferase, wherein said acyltransferase transfers an aromatic acyl group to the glucose of the 3 or 5 position of anthocyanin or that transfers an aromatic acyl group to flavonoid, or said polynucleotides produced by cloning with the primer SEQ ID NO: 21 or those that hybridize to said primer or to nucleotide sequences encoding SEQ ID NO: 1-6 and having said protein activity, and plant/plant cells comprising said polynucleotides or methods of stabilizing, altering or acylating a pigment of a flower with exemplified or non-exemplified polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in previous Office actions. Applicant's arguments filed 05/19/03 have been considered but not all are persuasive.

Applicant's arguments that the instant specification enables the invention as broadly claimed are not persuasive for the reasons of record. The scope of the claims encompass any and all polynucleotides from any source having the ability to transfer an

aromatic acyl group to the glucose of the 3 or 5 position of anthocyanin or an aromatic acyl group to any flavonoid, and said polynucleotides produced by cloning with the primer SEQ ID NO: 22 or those that hybridize to said primer or to nucleotide sequences of SEQ ID NO: 1-6 and encoding a protein having said aromatic acyltransferase activity. In contrast, the instant specification provides guidance for the polynucleotides of SEQ ID NO: 1-6. The working examples demonstrate that the proteins encoded by SEQ ID NO: 1-6 have aromatic acyl transferase activity in yeast and E.coli. Applicant has not provided guidance for the vast number of other cDNAs from other plant sources encoding said enzyme activity.

The state of the art for the isolation of cDNA or genomic clones with a defined functionality is highly unpredictable. Applicant's own specification admits (on pages 5 and 6) that prior to this invention all attempts to purify aromatic acyltransferase had failed. While the cDNAs disclosed in Examples 6, 8 and 20 were obtained using a hybridization method, the specific hybridization conditions used to obtain said cDNAs are not recited in the rejected claims. In addition, the hybridization conditions as set forth in the claims or the single primer of SEQ ID NO: 22 are not expected to yield polynucleotides that are functionally related to SEQ ID NO: 1-6, as stated in the last Office action. Note, SEQ ID NO: 1-6 are DNA sequences not amino acid sequences.

Regarding claims that recite % of sequence identity, Applicant has not provided guidance with respect to the regions of the disclosed sequence, which can be modified so as polynucleotides having both the structural and functional properties as recited in the claims can be obtained. In the absence of such guidance, undue trial and error

experimentation would be required to screen through the vast number of different polynucleotides having the recited structural properties (% of identity) to identify those having the ability to transfer aromatic acyltransferase activity to flavonoid or to glucose position 3 or 5 of anthocyanin. In addition, the specification is not enabling for a transformed animal cell because no expression vector for transformation of animal cells has been disclosed. The specification fails to provide guidance for a method of stabilizing or altering a pigment in a plant by expressing exemplified or non-exemplified polynucleotide in the plant. No transgenic plant with altered pigment has been disclosed. The state of the prior art teaches that stability of a pigment is controlled by a number of factors including light, heat, pH and other enzymes (Löpez-serrano et al. (J. Agric. Food Chem. 1999, vol 47, pp. 824-827). The instant specification does not disclose or even suggest the existence of these factors and additional enzymes required for pigment stability or alteration. Given the lack of sufficient guidance in the specification, one skilled in the art would have to go through trail and error experimentation considered undue.

In *Genentech Inc. v. Novo Nordisk* A/S (42 USPQ2d 1001 at p. 1005) The CAFC stated "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not workable...While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention...[W]hen there is no

disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required...."

Therefore, for the reasons discussed above and in the last Office action, the claimed invention is not enabled throughout the broad scope.

Written Description

Claims 1-3, 5-12, 20, 22-41 and 46-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in previous Office actions. Applicant's arguments filed 05/19/03 have been considered but are not persuasive..

Applicant argues that the instant specification describes cloning of many cDNAs that encode an enzyme having an aromatic acyltransferase activity and the cloned cDNAs. Applicant also argues that a core structure, namely, SEQ ID NO: 22 common to aromatic acetyltransferase gene family, which would allow a skilled artisan to visualize the identity of the species within the genus, is described. Therefore, Applicant asserts that the specification provides sufficient written description for the polynucleotides as broadly claimed.

These arguments are not persuasive because Applicant has not described a representative number of polynucleotides of the genus claimed because SEQ ID NO: 1-6 are from related plant species. Applicant has not described functional domains of the

disclosed anthocyanin aromatic acyltransferases (3 or 5AT). The prior art does not amend the deficiency. The core structure, namely, SEQ ID NO: 22 is not specific to aromatic acytransferase gene family.

In *Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), the court stated:

An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties", not a mere wish or plan for obtaining the claimed chemical invention... Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself (43 USPQ2d at 1404).

The court held that held that human insulin-encoding cDNA is not described by prophetic example, which sets forth only a general method for obtaining the human cDNA:

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity...Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes...does not necessarily describe the DNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA....Accordingly, the specification does not provide a written description of human cDNA (43 USPQ2d at 1405).

The description of a single species of rat cDNA was held insufficient to describe the broad genera of vertebrate or mammalian insulin:

"In claims to genetic material...a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It doesn't define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function...does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is (43 USPQ2d at 1406).

The court continued:

"Thus...a cDNA is not defined by the mere name 'cDNA', even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA...A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus". (43 USPQ2d at 1406). See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Applicant has not described the composition and structure of the polynucleotides as broadly claimed. Consequently, the specification has not provided an adequate description for expression vectors, host cells, and plants comprising said DNA, and a method that employs said polynucleotides.

Therefore, for the reasons discussed above and in the last Office actions, the claimed invention does not meet the current written description requirements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6, 9-12, 20, 22-41, 46, 48 and 51-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Brugliera (WO 94/03591).

The claims are drawn to an isolated polynucleotide encoding an anthocyanin acyltransferase that transfers an aromatic acyl group to the glucose of the 3, 5 position

of anthocyanin or aromatic acyltransferase of a flavonoid, and said polynucleotide that hybridizes to SEQ ID NO: 1-6 or 22 under hybridization conditions as recited in the claims, and encoding a protein having said acetyltransferase activity, a vector, plant cell, microbial cell, and cut flower of said plant, and a method of altering the color of flowers by expressing said polynucleotide.

Brugliera teaches an isolated DNA encoding flavonoid-3-glucotransferase (3RT). The cited reference also teaches vectors for transformation of plants/cells, cut flowers, and transgenic plant with altered flower pigment (Examples 10-14 and Table 5). Given that claims 1, 9-12, 20, 22-27 and 46 do not recite specific structural characteristics such as sequences that distinguish the claimed polynucleotide from those of the prior art, and given that the hybridization conditions recited in claims 5-6, 28-41, 48, and 51-52 do not specify wash time, all claim limitations are taught by Brugliera.

Remarks

Claims 7-8, 49-50 and 54-66 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide encoding a protein having at least 30% or 69% sequence identity to the protein encoded by SEQ ID NO: 1-6, host cells, plants/plant cells comprising said polynucleotide; nor that the prior art teaches a method that employs said polynucleotide.

Claims 54-66 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and After final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

3/5/04
Mai

Medina A. Ibrahim